Chapter 4

How the Risk Assessments Identified Pollutant Limits for Biosolids

The goal of the Part 503 biosolids risk assessments was to establish risk-based pollutant limits that protect human health and the environment from reasonably anticipated adverse effects of pollutants in biosolids. EPA used four types of information in its biosolids risk assessments:

- ***Available Scientific Data*** (e.g., toxicity factors commonly used by EPA, such as RfDs or q_1*s, were used to identify adverse effects associated with specific concentrations of pollutants; field study data were used to determine plant uptake of pollutants from biosolids-amended soils).
- ***Assumptions*** when specific information was not available (e.g., 70-year lifetime exposure was assumed for most pathways; assumptions were made regarding quantities of food grown on land amended with biosolids; and linear uptake of pollutants by plants was assumed).
- ***Policy decisions*** when specific scientific data regarding risks were unavailable (e.g., a cancer risk level of 1×10^{-4} was used).
- New or existing ***methodologies*** (e.g., development of a new method for estimating food consumption; for the ground-water pathway, the VADOFT and AT123D computer models were used to estimate pollutant transport through the environment).

How Pollutant Limits Were Derived in the Revised Risk Assessments

This chapter explains how EPA used the revised biosolids risk assessments to develop pollutant limits for evaluated exposure pathways, from which the final Part 503 pollutant limits were selected. The process of developing pollutant limits involved:

- Determining and defining factors to be used in calculating pollutant limits
- Selecting key data, assumptions, and methods to be used, and making related policy decisions as needed

- Performing risk assessment calculations

In describing each of these steps, this chapter provides example risk assessment calculations for several exposure pathways; explanations of how a Part 503 pollutant limit was selected for land application, surface disposal, and incineration of biosolids; and a detailed discussion of the risk assessment conducted for cadmium in land-applied biosolids, exposure pathway 2.

Parameters, Assumptions, Policy Decisions, and Methods Used

The biosolids risk assessments used a series of ***algorithms***, or equations, that mathematically represented each exposure pathway to calculate pollutant limits. A biosolids ***pollutant limit*** is the pollutant loading rate or concentration of a particular pollutant in biosolids that would not be expected to harm public health or the environment via the pathway being evaluated when biosolids are land applied or placed on a surface disposal site. Pollutant limits for the incineration of biosolids protect only public health because ecological pathways were not evaluated.

Each set of algorithms contained a sufficient number of ***parameters*** (appropriate input factors) for calculating the pollutant limits. Some of the parameters used in the algorithms were readily available, such as standard toxicity factors used by EPA (i.e., RfDs or q_1*s). Other parameters had to be calculated using an appropriate methodology, or were selected based on assumptions and/or policy decisions. An example of an assumption is the percentage of food grown on biosolids-amended soils—known as the FC parameter.

Table 6 (in Chapter 2) summarizes the exposure pathways used in the risk assessment for land application and provides a quick reference regarding when certain parameters were used (e.g., for pathways evaluating human, animal, or plant exposures.) For more information on the development of the exposure pathways, see Chapter 2.

Land Application Risk Assessment

All of the parameters used in the different algorithms for conducting the biosolids land application risk assessment are defined in Appendix A. The methodologies (i.e., approach or basis), assumptions, and policy decisions used to establish numeric values for the parameters in the land application risk assessment are described in Appendix B; this table also indicates whether a parameter is conservative or average, and why. How these parameters were used is discussed below.

Risk Assessment Calculations

For all exposure pathways for land application, an allowable dose of each pollutant was identified (e.g., based on an RfD or q_1* for humans; or an appropriate representation of allowable dose for animals, such as a "threshold pollutant intake," or TPI). Initially, this allowable dose included pollutant exposure from all sources (biosolids, food, air, and water). Exposure from sources other than biosolids were then subtracted from the total allowable dose. The resulting value indicated the allowable dose of a pollutant from biosolids only (e.g., an RIA, see Appendices A and B). This health parameter was then combined with pollutant intake information (e.g., the amount of a pollutant in biosolids taken up by plants that are then ingested by humans; the amount of a particular food consumed) to derive a pollutant limit.

The selected or calculated values for the parameters (e.g., see Box 9, Chart A, and Box 10, Chart B) were used in algorithms specific to each exposure pathway to calculate pollutant limits. For many of the exposure pathways, calculating pollutant limits involved two or more algorithms. For example, the first algorithm might involve calculating a health-based parameter (e.g., an RIA), followed by one or more interim calculations that relate the health parameter to a pollutant concentration, and a final algorithm that calculates a pollutant limit (an RP or RSC).

Examples of several biosolids risk assessment calculations for land application are shown in Boxes 9 through 14. These examples illustrate how different parameters and algorithms were used to calculate limits for organic and inorganic pollutants that would protect humans, animals, and plants from reasonably anticipated adverse effects via the different exposure pathways. As shown in Box 9, two algorithms were needed to calculate the pollutant limit for arsenic for exposure involving an adult eating crops via Pathway 1. As shown in Box 14, seven different algorithms were needed to calculate the PCB pollutant limit for an adult drinking surface water and ingesting fish from water that had been subjected to runoff from biosolids-amended soils.

Approach Used for the Surface Disposal Risk Assessment

Thus far, examples of how the biosolids risk assessments were conducted have focused on land application. Somewhat different approaches were used to determine pollutant limits for surface disposal and incineration of biosolids, as discussed below.

The risk assessment for surface disposal of biosolids evaluated risks associated with:

- ***Monofills*** (which contain biosolids with a solids content generally of 20 percent or greater) and ***surface impoundments*** (which contain liquid and sediment layers), both lined and unlined, to represent the variety of surface disposal sites.
- Human exposure to pollutants in biosolids through ***ground water*** (from drinking water from different classes of ground water, i.e., Class I, II, and III, according to EPA's ground-water classification system). For the ground-water pathway, lined units generally reduced pollutant transport risks to ground water but increased volatilization risks.
- Human exposure to pollutants in biosolids through ***inhalation of air*** containing pollutants present in biosolids (the vapor, or air, pathway).

Risk-based criteria were developed for Class I and Class II/III ground water. A framework established by EPA for federal and state policymaking efforts concerning ground-water protection (*Ground-Water Protection Strategy*, 54 FR 5812, February 6, 1989) provides the following category definitions:

- *Class I.* An existing source of drinking water of unusually high value that is vulnerable to contamination and is either irreplaceable as a source of drinking water for substantial numbers of people or is ecologically vital (i.e., as habitat for rare or endangered species).
- *Class II.* All non-Class I ground water currently used for, or potentially available for, drinking water.
- *Class III.* Ground water that is not being used as a source of drinking water due to high concentrations of total dissolved solids or pollutants or because the yields are too low to meet the needs of an average household.

Upon completion of the biosolids risk assessment, EPA made a policy decision to regard all ground water as drinkable in accordance with EPA's Class II designation.

Box 9
Example Risk Assessment Calculation: Arsenic for an Adult Person Ingesting Crops Grown in Biosolids-Amended Soils (Pathway 1)

This example illustrates the method used to calculate pollutant limits for inorganic, noncarcinogenic pollutants.

Goal: Calculate the amount of pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without reasonably anticipated adverse effects to humans. This level is defined as the *reference application rate of a pollutant (RP)*. If the pollutant in question is inorganic (like arsenic), then it does not degrade in the environment but accumulates as additional biosolids are added to soils.

Note: The exposure pathway discussed in this example is Pathway 1, in which biosolids are applied to soils, plants are grown in the biosolids-amended soils, and humans eat the plants grown there. Appendices A and B provide additional information on how the parameters presented below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3$$

$$\begin{matrix}\textit{Adjusted reference} \\ \textit{intake of pollutant} \\ \textit{in humans (RIA)}\end{matrix} = \left(\frac{\begin{matrix}\textit{Oral reference} \\ \textit{dose (RfD)}\end{matrix} \times \begin{matrix}\textit{Body weight} \\ \textit{(BW)}\end{matrix}}{\begin{matrix}\textit{Relative effectiveness of} \\ \textit{ingestion exposure (RE)}\end{matrix}} - \begin{matrix}\textit{Total background} \\ \textit{intake rate from} \\ \textit{all sources (TBI)}\end{matrix}\right) \times 10^3$$

RIA = Amount of additional pollutant ingested by humans without expectation of adverse effects (i.e., the allowable dose).

RfD = Amount of intake of a noncarcinogenic, usually inorganic, pollutant without appreciable risk. RfDs usually are developed in specialized, small animal studies to determine the level of a pollutant above which toxic responses begin to occur. These studies involve extrapolation and the application of safety factors to estimate the safe level of pollutant intake by humans.

BW = Human body weight.

RE = Relative effectiveness of exposure, which accounts for differences in bioavailability if a pollutant is ingested in food or water or is inhaled. Because of limited data, this value was set at 1.0.

TBI = Total pollutant intake from all background sources in water, food, and air.

Step 2:

$$RP_c = \frac{RIA}{Sum(UC \cdot DC \cdot FC)}$$

$$\begin{matrix}\textit{Reference cumulative} \\ \textit{application rate of} \\ \textit{pollutant } (RP_c)\end{matrix} = \frac{\textit{Adjusted reference intake of pollutant in humans (RIA)}}{\sum \begin{matrix}\textit{Uptake response} \\ \textit{of pollutant} \\ \textit{in plants (UC)}\end{matrix} \times \begin{matrix}\textit{Daily dietary} \\ \textit{consumption of} \\ \textit{food group (DC)}\end{matrix} \times \begin{matrix}\textit{Fraction of food} \\ \textit{grown in} \\ \textit{biosolids-amended} \\ \textit{soils (FC)}\end{matrix}}$$

RP_c = The cumulative amount of a pollutant that can be land applied without adverse effects from biosolids exposure via the pathway evaluated.

RIA = Amount of pollutant ingested by humans without expectation of adverse effects (i.e., allowable dose).

UC = Plant uptake slope for pollutant from soils/biosolids.

DC = Dietary consumption of different food groups grown in soils amended with biosolids.

FC = Fraction of different food groups assumed to be grown in soils amended with biosolids.

Box 9 (Continued)

Calculation of the Arsenic Pollutant Limit for Pathway 1

Step 1 Parameters:

Parameter	Value	Units
RfD	0.0008	milligrams per kilogram per day (mg/kg · day)
BW	70	kilograms (kg)
RE	1.0	no units
TBI	0.012	milligrams pollutant per day (mg/day)
10^3	103	conversion factor, micrograms per milligram (µg/mg)

Step 1 Calculation:

$$RIA = \frac{RfD \cdot BW}{RE} - TBI \cdot 10^3 = \frac{0.0008 \cdot 70}{1.0} - 0.012 \cdot 10^3 = 44\ \mu g\ arsenic/g\text{–}day$$

Step 2 Parameters:

Parameter	Value	Units
RIA	44	micrograms pollutant per day (µg/day)
UC		micrograms pollutant per gram of dry plant tissue (µg/g DW)/kg–pollutant/hectare
DC		dry grams of food group in the diet per day (g DW/day)
FC		no units

$\sum UC \cdot DC \cdot FC = 0.00654$ *from Chart A*

Chart A

Values for Parameters Used in Calculating the Pollutant Limit for Arsenic, Pathway 1

Food Group	UC	DC	FC	UC · DC · FC
Potatoes	0.002	15.5954	0.025	0.00073
Leafy vegetables	0.018	1.9672	0.025	0.00091
Legumes	0.001	8.7462	0.025	0.00024
Root vegetables	0.004	1.5950	0.025	0.00015
Garden fruits	0.001	4.1517	0.025	0.00015
Peanuts	0.001	2.2538	0.025	0.00006
Grains and cereals	0.002	96.6802	0.025	0.00430
Sum UC · DC · FC				0.00654

Other Variables	
RfD	0.0008
BW	70
RE	1
TBI	0.121
RIA	44
RP_c	6,700

Step 2 Calculation:

$$RP_c = \frac{RIA}{\sum UC \cdot DC \cdot FC} = \frac{44}{0.00654} = 6{,}700\ kg/ha\ of\ arsenic\ biosolids\ (rounded)$$

Note: The most limiting pathway for arsenic was Pathway 3 (see Box 11).

Box 10
Example Risk Assessment Calculation: PCBs for an Adult Person Ingesting Crops Grown in Biosolids-Amended Soils (Pathway 1)

This example illustrates the method used to calculate pollutant limits for degradable, carcinogenic organic pollutants.

Goal: Calculate the amount of pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without reasonably anticipated adverse effects to humans. This level is defined as the *reference application rate of a pollutant (RP)*. The RP for organic pollutants (e.g., PCBs), which degrade in the environment, is an annual application rate (rather than a cumulative loading rate as was used for inorganic pollutants, as in Box 9).

Note: The exposure pathway discussed in this example is Pathway 1, in which biosolids are applied to soils, plants are grown in the biosolids-amended soils, and humans eat the plants grown there. Appendices A and B provide additional information on how the parameters presented below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RIA = \left(\frac{RL \cdot BW}{q_1{*} \cdot RE} - TBI \right) \cdot 10^3$$

$$\begin{matrix}\textit{Adjusted reference} \\ \textit{intake of pollutant} \\ \textit{in humans (RIA)}\end{matrix} = \left(\frac{\textit{Risk level (RL) x Body weight (BW)}}{\begin{matrix}\textit{Human cancer} \\ \textit{potency } (q_1{*})\end{matrix} \times \begin{matrix}\textit{Relative} \\ \textit{effectiveness} \\ \textit{of ingestion} \\ \textit{exposure (RE)}\end{matrix}} - \begin{matrix}\textit{Total} \\ \textit{background} \\ \textit{intake rate} \\ \textit{from all} \\ \textit{sources (TBI)}\end{matrix} \right) \times 10^3$$

RIA = Amount of additional pollutant ingested per day by humans without expectation of adverse effects (i.e., the allowable dose).

RL = Cancer risk level. The probability that one additional cancer case could be expected to occur in that part of the population that is exposed. For the biosolids risk assessment, the RL was 1×10^{-4}. This risk is equivalent to the probability of one additional cancer case in a population of 10,000 exposed individuals. Note: The exposed population may be only a small fraction of the total population.

BW = Human body weight.

$q_1{*}$ = Cancer potency value. The $q_1{*}$ factor is the amount of intake of a chemical (organic or inorganic) that results in a specified estimate of cancer risk. The assumption is made that even one molecule of a cancer-causing compound will have some risk. $Q_1{*}$s usually are developed in specialized, small-animal studies. These studies involve extrapolation and the application of safety factors to estimate an acceptable level of pollutant intake by humans. $Q_1{*}$s are conservative estimates (i.e., contain relatively large safety factors).

RE = Relative effectiveness of exposure, which accounts for differences in bioavailability if the pollutant is ingested in food or water or is inhaled. Because of limited data, this value was set at 1.0.

TBI = Total intake of the pollutant from all background sources in water, food, and air—assumed negligible because organic PCB compounds are considered degradable.

Box 10 (Continued)

Step 2:

$$RLC = \frac{RIA}{\sum UC \cdot DC \cdot FC}$$

$$\begin{matrix}\textit{Reference} \\ \textit{concentration} \\ \textit{of pollutant} \\ \textit{in soil } (RLC)\end{matrix} = \frac{\textit{Adjusted reference intake of pollutant in humans } (RIA)}{\begin{matrix}\textit{Uptake response} \\ \textit{of pollutant} \\ \textit{in plants } (UC)\end{matrix} \times \begin{matrix}\textit{Daily dietary} \\ \textit{consumption} \\ \textit{of food group} \\ (DC)\end{matrix} \times \begin{matrix}\textit{Fraction of food} \\ \textit{group grown in} \\ \textit{biosolids–amended} \\ \textit{soil } (FC)\end{matrix}}$$

RLC = Pollutant concentration in soil considered to be without expectation of adverse effect for animals or humans.
UC = Plant uptake slope for pollutant from soils/biosolids.
DC = Dietary consumption of different food groups grown on land amended with biosolids.
FC = Fraction of different food groups assumed to be grown on land amended with biosolids.

Step 3:

$$k = \frac{ln2}{T_{0.5}}$$

$$\textit{First–order decay rate constant } (k) = \frac{\textit{Logarithm factor } (ln2)}{\textit{Time factor } (T_{0.5})}$$

k = First-order decay rate constant (yr^{-1})
ln = Natural logarithm
$T_{0.5}$ = Half-life of pollutant in soil (yr)

Step 4:

$$RP = RLC \cdot MS \cdot 10^{-9} \cdot [1 + e^{-k} + e^{-2k} + ... + e^{(1-n)k}]^{-1}$$

$$\begin{matrix}\textit{Reference annual} \\ \textit{application} \\ \textit{rate of} \\ \textit{pollutant} (RP)\end{matrix} = \begin{matrix}\textit{Reference} \\ \textit{concentration of} \\ \textit{pollutant in} \\ \textit{soil } (RLC)\end{matrix} \times \begin{matrix}\textit{Weight of} \\ \textit{upper 15 cm} \\ \textit{of soil } (MS)\end{matrix} \times \begin{matrix}\textit{Decay} \\ \textit{factor} \\ (k)\end{matrix}$$

RP_a = The amount of a pollutant that can be applied to a hectare of land per year without expectation of adverse effects.
MS = Assumed mass of dry soil in the upper 15 centimeters of soil.
10^{-9} = Conversion factor.
e = Base of natural logarithms, 2.718.
k = Loss rate constant.
n = Number of years of application until equilibrium conditions reached.

Box 10 (Continued)

Calculation of the PCB Limit for Pathway 1

Step 1 Parameters:

Parameter	Value	Units
RL	10^{-4}	no units
BW	70	kilograms (kg)
q_1*	7.7	milligrams per kilogram (mg/kg) · day
RE	1.0	no units
TBI	0.0	milligrams pollutant per day (mg/day)
10^3	10^3	conversion factor, micrograms per milligram (µg/mg)

Step 1 Calculation:

$$RIA = \frac{RL \cdot BW}{q_1* \cdot RE} - TBI \cdot 10^3 = \frac{10^{-4} \cdot 70}{7.7 \times 1.0} \cdot 10^{-3} = 0.909\ \mu g/day$$

Step 2 Parameters:

Parameter	Value	Units
RIA	0.909	micrograms pollutant per day (µg/day)
UC		micrograms pollutant per gram dry plant tissue (µg/g DW)/kg-pollutant/hectare
DC		dry grams of food group in the diet per day (g DW/day)
FC		no units

$\sum (UC \cdot DC \cdot FC = 0.00312$ *from Chart B*)

Chart B

Values for Parameters Used in Calculating the Pollutant Limit for PCBs, Pathway 1

Food Group	UC	DC	FC	UC · DC · FC	Other Variables	
Potatoes	0.001	15.5954	0.025	0.00039	RL	$1 \cdot 10^{-4}$
Leafy vegetables	0.001	1.9672	0.025	0.00005	BW	70
Legumes	0.001	8.7462	0.025	0.00022	q_1*	7.7
Root vegetables	0.001	1.5950	0.025	0.00004	RE	1
Garden fruits	0.001	4.1517	0.025	0.00010	DE	1
Peanuts	0.001	2.2538	0.025	0.00006	MS	$2 \cdot 10^9$
Grains and cereals	0.001	90.6802	0.025	0.00227	k	0.063
Sum UC · DC · FC				0.00312	RIA	0.909
					RLC	290.934
					RP_a	37

Box 10 (Continued)

Step 2 Calculation:

$$RLC = \frac{RIA}{\sum UC \cdot DC \cdot FC} = \frac{0.909}{0.00312} = 291\ \mu g/g\ soil\ DW$$

Step 3 Calculation:

$$k = \frac{ln2}{T_{0.5}} = 0.063\ yr^{-1}$$

Step 4 Parameters:

Parameter	Value	Units
RLC	37	kilogram PCB per hectare per year (kg PCB/ha/yr)
MS	$2 \cdot 10^{-9}$	grams soil dry weight per hectare (g soil DW/ha)
k	0.063	(yr^{-1})
e	2.718	no units
n	100	assumed years of application required to reach equilibrium

Step 4 Calculation:

$$RP_a = RLC \cdot MS \cdot 10^{-9} \cdot [1 + e^{-k} + e^{-2k} + \ldots e^{(1-n)k}]^{-1} =$$

$$291 \cdot (2 \cdot 10^{9}) \cdot 10^{-9} \cdot [e^{-0.063} + e^{-2 \times 0.063} \ldots e^{(1-100)}\ x\ 0.063]^{-1} =$$

$$37\ kg\ PCBs/ha/yr$$

Note: The most limiting pathway for PCBs was Pathway 5; however, PCBs were not included in the final rule (see Chapter 3).

Box 11
Example Risk Assessment Calculation: Arsenic for a Child Ingesting Biosolids (Pathway 3)

This example illustrates the method used to calculate pollutant limits for children for inorganic chemicals, based on RfDs (see Box 3); the method is similar for organic pollutants, except that q_1*s and cancer risk levels were used instead of RfDs. The same method was used for inorganic and organic pollutants because this pathway conservatively assumes the direct ingestion of biosolids by a child without the biosolids pollutants having had an opportunity to degrade or to otherwise be reduced by being mixed into soils.

Goal: Calculate the concentration of the pollutant in biosolids that can be ingested by a child consuming biosolids without expectation of adverse effects. This level is known as the reference concentration of a pollutant in biosolids (RSC).

Note: The exposure pathway discussed in this example is Pathway 3, which involves a child eating biosolids that have not been mixed with soil. Appendices A and B provide additional information about how the parameters presented below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3$$

This step is similar to Step 1 in Box 9, which shows an example calculation for an adult ingesting crops grown on land to which biosolids have been applied. The major difference in this example is that the body weight for a child is used (versus the adult body weight in the example in Box 9).

Step 2:

$$RSC = \frac{RIA}{I_s \cdot DE}$$

$$\begin{matrix}\textit{Reference concentration of} \\ \textit{pollutant in biosolids (RSC)}\end{matrix} = \frac{RIA}{\begin{matrix}\textit{Biosolids ingestion} \\ \textit{rate } (I_s)\end{matrix} \times \begin{matrix}\textit{Exposure duration} \\ \textit{adjustment (DE)}\end{matrix}}$$

RSC = The concentration of a pollutant in biosolids that can be ingested without expectation of adverse effects.

RIA = The amount of pollutant ingested by humans without expectation of adverse effects (i.e., allowable dose).

I_s = The rate of biosolids ingestion by children.

DE = Exposure duration adjustment. This parameter attempts to include considerations of less-than-lifetime exposures by children, because the RfDs used in Step 1 are based on lifetime (i.e., adult) exposure. Because no EPA-approved method was available for such adjustments prior to promulgating the Part 503 rule, the DE was set at 1.

Calculation of the Arsenic Limit for Pathway 3

Step 1 Variables:

Parameter	Value	Units
RfD	0.0008	milligrams pollutant per kilogram BW per day (mg/kg/day)
BW	16	kilograms (kg) for a 1-to-6-year-old child
RE	1.0	no units
TBI	0.0045	milligrams pollutant per day (mg/day)
10^3	10^3	conversion factor, micrograms per milligram (µg/mg)

Box 11 (Continued)

Step 1 Calculation:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3 = \left(\frac{0.0008 \cdot 16}{1.0} - 0.0045\right) \cdot 10^3 = 8.3\ \mu g\ arsenic/g\text{-}day$$

Step 2 Parameters:

Parameter	Value	Units
RIA	8.3	micrograms pollutant per day (µg/day)
I_s	0.2	grams of soil DW per day (g/day)
DE	1	no units

Step 2 Calculation:

$$RSC = \frac{RIA}{I_s \cdot DE} = \frac{8.3}{0.2 \cdot 1} = 41\ \mu g\ \ of\ \ arsenic/g\ of\,biosolids\ DW\,(rounded)$$

Note: Pathway 3 was the most limiting pathway for arsenic.

Grain is one of many crops grown in soils amended with biosolids.

Box 12
Example Risk Assessment Calculation: Arsenic for an Animal Ingesting Plants Grown on Biosolids-Amended Soils (Pathway 6)

This example illustrates one method used to calculate pollutant limits for animals for inorganic chemicals. The most sensitive/most exposed animal species varied according to the particular pollutant.

Goal: Calculate the amount of each pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without adverse effects to animals. This level is defined as the *reference application rate of a pollutant (RP).*

Note: The exposure pathway discussed in this example is Pathway 6, which involves the application of biosolids to soil, the uptake of biosolids pollutants in soil by plants, and the consumption of these plants by animals. In this case, pollutant transfer began with forage plants taking up the pollutant from biosolids-amended soils; this forage then constituted 100 percent of the animal's diet. Appendices A and B provide additional information about how the parameters described below were used to determine pollutant limits for biosolids.

Description of the Algorithm

Step 1:

$$RF = TPI - BC$$

$$\begin{matrix}\textit{Reference concentration of} \\ \textit{pollutant in forage (RF)}\end{matrix} = \begin{matrix}\textit{Threshold pollutant} \\ \textit{intake level (TPI)}\end{matrix} - \begin{matrix}\textit{Background concentration of} \\ \textit{pollutant in forage (BC)}\end{matrix}$$

RF = The allowable concentration of a pollutant in the animal diet from forage grown in biosolids-amended soils.
TPI = The maximum pollutant intake level in the animal diet without observed toxic effect on the most sensitive or most exposed species (based on National Research Council data).
BC = The background concentration of pollutant in forage tissue.

Step 2:

$$RP = \frac{RF}{UC}$$

RP = The amount of a pollutant that can be applied to a hectare of land without expectation of adverse effects.
RF = The allowable concentration of a pollutant in the animal diet from forage grown on biosolids-amended soils.
UC = Plant uptake of pollutants from soil/biosolids (see Chapter 3 for a detailed discussion of plant uptake of pollutants).

Calculation of the Arsenic Limit for Pathway 6

Step 1 Parameters:

Parameter	Value	Units
TPI	50	micrograms of pollutant per gram of forage (grown in biosolids-amended soils) in diet DW (µg/g DW)
BC	0.304	Micrograms of pollutant per gram of forage tissue DW(µg/g DW)

Step 1 Calculation:

$$RF = TPI - BC = 50 - 0.304 = 49.7 \text{ } (\mu g \textit{ pollutant/g diet DW})$$

Box 12 (Continued)

Step 2 Parameters:

Parameter	Value	Units
RF	49.7	micrograms of pollutant per gram of diet DW (μg/g DW)
UC	0.030	(micrograms of pollutant per gram of plant tissue DW) (kilograms of pollutant per hectare)$^{-1}$ (μg/g DW) (kg/ha)$^{-1}$

Step 2 Calculation:

$$RP_c = \frac{RF}{UC} = \frac{49.7}{0.030} = 1{,}600\ kg\ arsenic/ha\,(rounded)$$

Note: The most limiting pathway for arsenic was Pathway 3 (see Box 11).

Carefully replicated field research yielded valid data for the Part 503 risk assessment for land application.

Box 13
Example Risk Assessment Calculation: Zinc for Plants Grown in Soils Amended With Biosolids (Pathway 8)

This example illustrates the method used to calculate pollutant limits for plants for inorganic chemicals; no organic pollutants were evaluated for this pathway because organics occur in biosolids at very low concentrations and are rarely taken up by plants in quantities beyond background levels.

Goal: Calculate the amount of each pollutant in biosolids that can be applied to a given area of land (e.g., hectare) without adverse effects to plants. This level is defined as the *reference application rate of a pollutant (RP).*

Note: The exposure pathway discussed in this example is Pathway 8, which involves the application of biosolids to soil and the uptake of pollutants in biosolids by plants. Pathway 8 involved determining RPs (defined above) by two different approaches and then choosing the more restrictive result from the two approaches as the pollutant limit. Chapter 3 and Appendices A and B provide more information about how the parameters described below were used to determine pollutant limits for biosolids.

Approach 1 - The Probability Approach:

1. A phytotoxicity threshold (PT_{50}) value—the concentration of a pollutant in plant tissue associated with a 50 percent retardation in growth of young tissue, which in turn was used to establish the concentration in plants associated with phytotoxicity—was identified for each pollutant from short-term experiment data on corn. The relationship between soil metal loading and resulting metal concentration in plant tissue was established based on studies in which only one metal element, often in the form of a metal salt, had been added to the growth medium (so that plant damage could be attributed to a specific metal).
2. A calculation was made to determine the probability that the metal concentrations in plants grown on soils amended with biosolids would exceed the PT_{50} at various metal loading ranges, using data only from field studies.
3. An acceptable level of tolerable risk of exceeding the PT_{50} was set at 0.01. That is, it was deemed acceptable to exceed the PT_{50} 1 out of every 100 times.
4. The highest biosolids loading rate having a less than 0.01 probability of causing the PT_{50} to be exceeded was the allowable loading rate—the RP.

For Zinc:

1. PT_{50} for zinc = 1,975 µg zinc/g plant tissue DW.
2. The probability that corn grown on biosolids-amended soils would exceed the PT_{50} was computed for 12 zinc loading ranges (e.g., from 0, 0-50, through 2,500-3,500 kg/ha).
3. As specified earlier, the acceptable level of tolerable risk for exceeding the PT_{50} was set at 0.01.
4. None of the loading rates evaluated exceeded the probability of 0.01 (see Chart C). Therefore, the highest loading rate evaluated was chosen as the allowable loading rate (the RP) for biosolids that would not cause a significant phytotoxic effect in corn: *RP = 3,500 kg zinc/ha.*

Box 13 (Continued)

Approach 2 - The Lowest-Observed-Adverse-Effects-Level (LOAEL) Approach:

Description of the Algorithm

$$RP = \frac{TPC - BC}{UC}$$

$$\text{Reference cumulative application rate of pollutant } (RP) = \frac{\text{Threshold phytotoxic concentration of pollutant in plant tissue } (TPC) - \text{Background concentration of pollutant in plant tissue } (BC)}{\text{Uptake response of pollutant in plant tissue } (UC)}$$

RP = The amount of a pollutant that can be applied to a hectare of land without expectation of adverse effects.
TPC = The concentration of a pollutant in a sensitive plant tissue species (e.g., lettuce, as opposed to a less sensitive species, such as corn, used in Approach 1) associated with the LOAEL, as an indication of phytotoxicity.
BC = Background concentration of pollutant in plant tissue.
UC = Plant uptake of pollutants from soil/biosolids (see Chapter 3 for a detailed discussion of plant uptake of pollutants).

For Zinc:

Parameters

Parameter	Value	Units
TPC	400	micrograms of pollutant per gram of plant tissue (lettuce) DW (µg/g DW)
BC	47.0	micrograms of pollutant per gram of plant tissue (lettuce) DW (µg/g DW)
UC	0.125	micrograms of pollutant per gram of plant tissue (lettuce) (kilograms of pollutant per hectare)$^{-1}$ (µg/g DW)(kg/ha)$^{-1}$

Calculation:

$$RP = \frac{TPC - BC}{UC} = \frac{400 - 47.0}{0.125} = 2{,}800 \; kg \; zinc/ha \; (rounded)$$

Results From Approaches 1 and 2

RP, *Approach* 1 = 3,500 *kg zinc/ha* RP, *Approach* 2 = 2,800 *kg zinc/ha*

The more restrictive result of the two approaches was chosen as the pollutant limit: *RP = 2,800 kg zinc/ha.* The limit set for Pathway 8 was the pollutant limit used in the Part 503 rule for zinc.

Box 13 (Continued)

Chart C

Probability of Zinc in Corn Grown on Biosolids-Amended Soils Exceeding the Phytotoxicity Tolerance Threshold

Zinc Loading Range (kg/ha)	Number of Observations	Probability of Exceeding Tolerance Threshold PT_{50} 1,975 µg/g
0	51	<0.0001
0-50	16	<0.0001
50-100	28	<0.0001
100-150	16	<0.0001
150-200	14	<0.0001
200-300	22	<0.0001
300-400	19	<0.0001
400-500	14	<0.0001
500-750	19	<0.0001
750-1,000	17	<0.0001
1,000-1,500	17	<0.0001
1,500-2,500	12	0.0020
2,500-3,500	10	<0.0001

Box 14
Example Risk Assessment Calculation: PCBs for an Adult Person Ingesting Surface Water and Fish Impacted by Pollutants in Runoff From Biosolids-Amended Soils (Pathway 12)

This example illustrates the method used to calculate pollutant limits for people (adults) for carcinogenic, organic pollutants evaluated in the biosolids land application risk assessment for surface water.

Goal: Calculate the amount of pollutant in biosolids that can be applied to a given area of land (e.g., kilograms per hectare per year) without adverse effects to humans. This level is defined as the *reference application rate of a pollutant (RP).*

Note: The exposure pathway discussed in this example is Pathway 12, which involves the application of biosolids to soil, the erosion of soil containing pollutants in biosolids, the transfer of the pollutants contained in the eroded soil to surface water, and the ingestion of the surface water and fish living in the surface water by humans. The calculations for surface water below have been summarized (i.e., not all calculations are presented) to simplify this example. For the more detailed calculations conducted for this pathway, see the *Technical Support Document for Land Application of Sewage Sludge* (U.S. EPA, 1992a). Appendices A and B provide more information about how the variables described below were used to determine pollutant limits for biosolids.

Description of Algorithm

Step 1: Mass Balance

The relative rates of pollutant loss for the site through erosion, volatilization, and leaching were calculated. These rates were then combined to give a total loss rate of pollutant from soil at the site (K). For Pathway 12, the ratio of the erosion loss rate to the total loss rate was then calculated to provide the fraction of pollutant loss caused by erosion (f_{ero}). For the additional calculations involved in the mass balance, see the *Technical Support Document for Land Application of Sewage Sludge* (U.S. EPA, 1992a).

$$f_{ero} = \frac{K_{ero}\ (yr^{-1})}{K_{tot}\ (yr^{-1})}$$

f_{ero} = fraction of total loss caused by erosion
K_{ero} = loss rate coefficient for erosion (yr-1)
K_{tot} = total loss rate for the pollutant in biosolids-amended soil (yr-1)

Step 2: Reference (Allowable) Intake of Pollutant (RI)

For carcinogenic pollutants (including some inorganics, i.e., arsenic):

$$RI = \frac{RL}{q_1{}^*}$$

For noncarcinogenic pollutants:

$$RI = RfD - background\ \ intake\ sources\ other\ than\ biosolids$$

Box 14 (Continued)

Step 3: Reference (Allowable) Water Concentration of Pollutant in Surface Water (RC_{sw}):

$$RC_{sw} = \frac{RI \cdot BW}{BCF \cdot FM \cdot P_t \cdot I_f \cdot + I_w}$$

RI = reference (allowable) intake
BW = body weight
BCF = pollutant-specific bioconcentration factor
FM = pollutant-specific food chain multiplier
P_f = ratio of pollutant concentration in the edible portion of fish to concentration in whole fish
I_f = daily consumption of fish
I_w = daily consumption of water

Step 4: Reference Concentration of Pollutant in Eroded Soil Entering the Stream (RC_{sed}):

$$RC_{sed} = RC_{sw}\ [KD_{sw} + \left(\frac{P_l}{P_s}\right)\left(\frac{1}{\rho_w}\right)]$$

RC_{sed} = reference concentration of pollutant in eroded soil entering the stream
RC_{sw} = reference water concentration for surface water
KD_{sw} = partition coefficient between solids and liquids within the stream
P_l = percent liquid in the water column
P_s = percent solids in the water column
ρ_w = density of water

Step 5: Dilution Factor (DF):

$$DF = \frac{A_{sma}\ S_{sma}}{A_{sma}\ \ S_{sma} + (A_{ws} - A_{sma})\ S_{ws}}$$

DF = dilution factor
A_{sma} = area affected by land application of biosolids (SMA=biosolids management area)
S_{sma} = sediment delivery ratio for the SMA
A_{ws} = area of the watershed (ha)
S_{ws} = sediment delivery ratio for the watershed

Note: The dilution factor (DF) describes how eroded soil from the SMA is diluted by soil from the untreated remainder of the watershed. It represents the fraction of the stream's sediment originating in the SMA. Step 5 assumes that rates of soil erosion from the SMA and the remainder of the watershed are the same; calculations for S_{sma} and S_{ws} were previously calculated but are not shown here (see *Technical Support Document* cited above for further information).

Box 14 (Continued)

Step 6: Reference Pollutant Concentration for Soil Eroding From the SMA (RC_{sma}):

$$RC_{sma} = \frac{RC_{sed}}{DF}$$

RC_{sma} = reference pollutant concentration in soil eroding from the SMA
RC_{sed} = reference concentration of pollutant in eroded soil entering the stream
DF = dilution factor

Step 7: Reference Annual Application Rate of Pollutant (RP_a):

$$RP_a = \frac{RC_{sma} \cdot ME_{sma} \cdot 10^{-6}}{f_{ero}}$$

RP_a = reference annual application rate of pollutant
RC_{sed} = reference pollutant concentration in soil eroding from the SMA
ME_{sma} = estimated rate of soil loss for the SMA
10^{-6} = conversion factor
f_{ero} = fraction of total loss caused by erosion

Calculation of the PCB Limit for Pathway 12

Parameter	Value	Units	Parameter	Value	Units
K_{ero}	0.004	yr^{-1}	$\frac{P_1}{P_s}$	62,500	unitless
K_{tot}	0.12	yr^{-1}	ρ_w	1	kg/1
RL	10^{-4}	lifetime	A_{sma}	1,074	ha
q_1^*	7.7	kg-day/mg	S_{sma}	0.46	unitless
RI	1.3×10^{-5}	mg/kg-day	A_{ws}	440,300	ha
BW	70	kg	S_{wa}	0.17	unitless
BCF	3.1×10^{-4}	l/kg	RC_{sed}	9.4×10^{-3}	mg/kg
FM	10	unitless	DF	0.0066	unitless
P_f	0.5	unitless	RC_{sma}	1.43	mg/kg
I_f	0.04	kg/day	ME_{sma}	8,400	kg/ha-yr
I_w	2	l/day	conversion factor	10^{-6}	kg/mg
RC_{sw}	1.5×10^{-7}	mg/l	f_{ero}	0.033	unitless
KD_{sw}	1,510	l/kg			

Box 14 (Continued)

Step 1 Calculation:

$$f_{ero} = \frac{K_{ero}\,(yr^{-1})}{K_{tot}\,(yr^{-1})} = \frac{0.004}{0.12} = 0.033$$

Step 2 Calculation:

$$RI = \frac{RL}{q_1*} = \frac{10^{-4}}{7.7} = 1.3 \times 10^{-5}\ mg/kg \cdot day$$

Step 3 Calculation:

$$RC_{sw} = \frac{RI \cdot BW}{BCF \cdot FM \cdot P_f \cdot I_f \cdot I_w} = \frac{(1.3\ x\ 10^{-5})\ (70)}{(3.1\ x\ 10^{-4})\ (10)\ (0.5)\ (0.04) + (2)} = 1.5 \times 10^{-7}\ mg/kg$$

Step 4 Calculation:

$$RC_{sed} = RC_{sw}\ [KD_{sw} + \left(\frac{P_1}{P_s}\right)\left(\frac{1}{\rho_w}\right)] = (1.5\ x\ 10^{-7})\ [(1{,}510) + (62{,}500)\ (1)] = 9.4\ x\ 10^{-3}\ mg/kg$$

Step 5 Calculation:

$$DF = \frac{A_{sma}\ S_{sma}}{A_{sma}\ S_{sma} + (A_{ws} - A_{sma})\ S_{ws}} = \frac{(1{,}074)\ (0.46)}{(1{,}074)\ (0.46) + [(440{,}300) - (1{,}074)]\ (0.17)} = 0.0066\ (unitless)$$

Step 6 Calculation:

$$RC_{sma} = \frac{RC_{sed}}{DF} = \frac{9.4 \times 10^{-3}}{0.0066} = 1.43\ mg/kg$$

Step 7 Calculation:

$$RP_a = \frac{RC_{sma} \cdot ME_{sma} \cdot 10^{-6}}{f_{ero}} = \frac{(1.43)\ (8.400)\ 10^{-6}}{(0.033)} = 0.348\ kg/ha \cdot yr$$

Note: The limiting pathway for PCBs is Pathway 3; however, organic pollutants, including PCBs, were not included in the final rule for land application (see Chapter 3).

Surface Disposal: Ground-Water Pathway

The risk assessment for the ground-water pathway for surface disposal of biosolids began with a mass balance that calculated pollutant loss to ground-water leaching, volatilization, effluent or water discharge (for surface impoundments), and degradation. An ***adjusted reference water concentration*** (RC_{gw}) for each pollutant, which was a health-based number based on MCLs or q_1*s, was calculated. Computer models (the VADOFT model for the unsaturated soil zone, and the AT123D model for the saturated zone) were then used to calculate pollutant transport to the ground water and lateral dispersion of the pollutant in the ground water beneath a surface disposal site.

Site-specific parameters for biosolids and ground water were used in the computer models (e.g., area and active lifetime of facility; thickness and porosity of the cover, if any; distance to well; solids concentrations of biosolids; soil type and porosity; depth to ground water; thickness of aquifer; net recharge or seepage; leaching rate; hydraulic conductivity). Chemical-specific factors also were used in the ground-water models (e.g., decay rates, diffusion and soil-water partition coefficients). The surface impoundment risk assessment also included inflow and outflow factors and exchange between the liquid and sediment layers.

Pollutant concentrations in nearby, downgradient well water were used to calculate seepage beneath the surface disposal facility, called the ***reference concentration of pollutant in water leaching from the monofill or seeping from the bottom of the surface impoundment*** (RC_{lec} or RC_{sep}), in milligrams per liter (mg/L). For monofills, the mass of solids in 1 m^3 of biosolids (MS) and the mass of biosolids in 1 hectare of a monofill (SC) were then calculated. (The SC was calculated by multiplying the depth of a monofill cell by the fraction of its total volume containing biosolids and the mass of solids per cubic meter of biosolids.) The RC, MS, SC, and well data were used to derive a ***reference concentration of pollutant*** in biosolids (RCS), expressed in milligrams per kilogram (mg/kg), which was identified as the risk-based pollutant limit.

Many of the assumptions made for the surface disposal ground-water pathway were conservative and probably contributed to overestimation of exposure and hence risk. Some of these assumptions included:

- A 150-meter distance to a downgradient receptor well for Class II/III aquifers, because no one drinks well water on site (based on EPA specifications for facilities that it regulates or on state requirements based on EPA regulations).
- The site life (i.e., the length of time a monofill receives biosolids, or the time it takes to fill a surface impoundment with biosolids) for monofills was assumed to be 20 years, and the site life for surface impoundments was assumed to be 7 years. After these periods, maximum pollutant loss (e.g., through leaching and volatilization) and pollutant concentrations in a receptor well were modeled for a 300-year period assuming a constant release of pollutants.
- For Class II/III aquifers, a 1-meter depth to ground water was assumed, which is less than the depth at most operating facilities. This conservative assumption is designed to protect aquifers at relatively shallow depths.
- Maximum pollutant concentrations at the 150-meter, downgradient well were calculated within the first 300 years after the life of the surface disposal site lapsed. In contrast, for the vapor pathway discussed below, a maximum 70-year average ambient air pollutant concentration was used.

Surface Disposal: Vapor (Air) Pathway

For the risk assessment for the vapor pathway for surface disposal of biosolids, the estimated volatile emissions of organic pollutants was first calculated. Inhalation volume and dispersion factors also were important parameters used. Expected concentrations of organic pollutants in ambient air at the property boundary of the surface disposal site were then calculated (using a simplified ISCLT model).

The health-based parameter for the vapor pathway was the ***reference air concentration for the pollutant*** (RC_{air}), expressed in micrograms per cubic meter ($\mu g/m^3$), which was based on q_1*s. A ***reference concentration of pollutant*** in biosolids (RCS) was then calculated, which was identified as the risk-based pollutant limit for the vapor pathway for surface disposal.

Approach Used for the Incineration Risk Assessment

One pathway was evaluated in the biosolids risk assessment for incineration—the inhalation pathway. A pathway to evaluate exposures to ingested pollutants from biosolids incineration was not evaluated because of limited procedural and data availability. In the inhalation pathway risk assessment, health-based ***risk-specific concentrations*** (RSCs) were calculated in an algorithm for arsenic, cadmium, chromium, and nickel. RSCs represented the allowable increase in average, daily ground-level ambient air concentrations above background levels for the pollutant from biosolids incineration. The RSC, based on q_1*s and inhalation rates, was then used in a second algorithm along with site-specific factors on:

- Pollutant dispersion in the ambient air
- Incinerator control efficiency
- Biosolids feed rate to the incinerator

The second algorithm identified risk-based pollutant limits for biosolids incineration, calculated as ***the allowable average daily concentration of the pollutant in biosolids*** (C), expressed in mg/kg of total solids (DW).

In addition to the RSCs and site-specific factors used to develop pollutant limits for biosolids incineration, an inhalation pathway pollutant limit also was developed for lead in biosolids that are incinerated based on 10 percent of the National Ambient Air Quality Standard (NAAQS) for lead. This percentage of the NAAQS for lead was substituted for the RSC and factored into the second algorithm along with site-specific factors, as discussed above, to identify a risk-based pollutant limit for lead in biosolids. Pollutant limits for beryllium and mercury in biosolids that are incinerated also were included in the final Part 503 rule, based on National Emissions Standards for Hazardous Air Pollutants (NESHAPS) for these two pollutants.

Pollutant limits for organic pollutants also were evaluated in the risk assessment for biosolids incineration. Organic pollutants associated with biosolids incineration, however, were regulated in the Part 503 rule through an "operational standard" (discussed below and in Chapter 5) that requires monitoring for and restrictions on emissions of total hydrocarbons (THCs) in the stack gas. An operational standard was used because not all of the organic pollutants in the incineration emissions (e.g., products of incomplete combustion) are known.

EPA estimated the risk for the technology-based THC operational standard using a weighted toxicity value for all organic pollutants for which there was a q_1*. This risk-based analysis first used parameters such as the 100-ppm THC standard and site-specific dispersion factors and gas flow rates to derive site-specific RSCs (discussed above). These RSCs, along with other parameters, including a weighted q_1*, an inhalation rate, and body weight, were then used to determine the degree of risk posed by the THC emission standard under site-specific conditions. (The "weighted" q_1* represented the cancer potency value for all organic compounds emitted from a biosolids incinerator that have the potential to create an adverse health effect, using data on 21 compounds in tests at eight biosolids incinerators, as well as data for numerous organics that were potentially present but not detected in the tests. The q_1* for each chemical was weighted in that it was multiplied by a "weighted fractional concentration" based on the compound's detected or assumed concentration.) The results of this risk assessment indicated that the risk associated with emissions at a 100-ppm THC level, based on data from 23 POTWs, did not exceed a 1×10^{-4} risk level, which was the level established in Part 503 to protect public health. Based on these results, in the EPA Administrator's judgment, the THC operational standard is protective of public health.

An amendment to the Part 503 rule allows carbon monoxide (CO) monitoring to be used in lieu of THC monitoring (see Chapter 2) because of good correlation between CO and THC levels. This amendment does not change the operational standard. If the CO is below 100 ppm when the emissions are monitored continuously, THCs in the emissions are assumed to be below 100 ppm.

Use of Risk Assessment Results and "The Most Limiting Pathway" Approach To Establish Part 503 Pollutant Limits

Calculating Exposure Pathway Pollutant Limits

Pollutant limits were calculated for each of the exposure pathways evaluated for the land application, surface disposal, and incineration risk assessments using the parameters and algorithms discussed above. The numeric results of these calculations are shown in Tables 10, 12, and 14.

Land Application Pollutant Limits

For land application, the calculation of pollutant limits warrants further explanation. Pollutant limits were first calculated separately for agricultural and non-agricultural lands (i.e., forest, public contact, and reclamation sites). The lower of the agricultural or non-agricultural pollutant limits was selected for each exposure pathway (see Table 10).

The pollutant limits for land application exposure pathways were expressed in different units for inorganic and organic pollutants to account for the fact that many organics degrade in the environment, in contrast to inorganics, which increase over time rather than degrade. This difference can be seen in Table 10 by the use of a cumulative application rate of pollutant (RP_c) for inorganics, expressed in kilograms of pollutant per hectare (kg-pollutant/ha), and an annual application rate of pollutant (RP_a) for most organics, expressed in kilograms of pollutant per hectare per year (kg-pollutant/ha-yr). In Pathways 1, 2, 4, and 11, RP_cs are listed for the organics aldrin/dieldrin and chlordane (and DDT for Pathway 11) because of their long halflife, while RP_as are listed for most other, degradable organics.

In some cases (Pathways 3, 5, and 7), a pollutant concentration in biosolids (an RSC) was used rather than a pollutant loading rate (a RP) to represent a pollutant limit when the pathway involved direct ingestion of biosolids. For further information

Table 10
Biosolids Risk Assessment Results for Land Application

Inorganic Pollutants:

Exposure Pathway	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Pollutant	RP_C	RP_C	RSC	RP_C	RSC	RP_C	RSC	RP_C	RP_C	RP_C	RP_C	RP_C	RP_C	RP_C
Arsenic	6700	930	41			1600	3100					66000		1200
Cadmium	610	120	39	1600	68000	140	650			53		63000		unlimited
Chromium			79000				190000	3000				unlimited		12000
Copper			10000			3700	2000	1500	2900			unlimited		unlimited
Lead			300			11000	1200			5000		unlimited		unlimited
Mercury	180	370	17	1500	24000							1100		unlimited
Molybdenum			400			18	530							
Nickel	63000	10000	820			1800	5400	420				unlimited		13000
Selenium	14000	1200	100	15000	13000	790	130							
Zinc	16000	3600	16000	150000	2200000	12000	36000	2800						

Organic Pollutants:

Exposure Pathway	1		2		3	4		5	6	7	8	9	10	11	12	13	14
Pollutant	RP_a	RP_C	RP_a	RP_C	RSC	RP_a	RP_C	RSC					RP_a	RP_C	RP_a	RP_a	RP_a
Aldrin/ Dieldrin		280		64	7.0		17	2.7						30000			
Benzo(a) pyrene	230		54		15										1.3	3500	unlimited
Chlordane		3400		790	86		13000	2300							5.3	3.9	unlimited
DDT	560		130		320	46		150						100000	1.2	45	unlimited
Heptachlor	990		220		24	65		7.4									
Hexachloro-benzene	320		75		70	25		29									
Hexachloro-butadiene	43000		10000		1400			600									
Lindane	2300		540		8.4	600		140							2100	110	unlimited
n-Nitrosodi-methylamine	87		20		2.1										29000	22	0.056
PCBs	37		8.5		14	2.4		4.6					0.50	200	0.34	1.4	unlimited
Toxaphene	2800		650		100	43		10							5.0	120	unlimited
Trichloro-ethylene	220000		51000		10000										unlimited	420	unlimited

Note: All results rounded down to two significant figures.

RP_C = reference cumulative application rate of pollutant (kg-pollutant/ha), used for inorganics and organics that do not degrade.

RSC = reference concentration of pollutant in biosolids (µg-pollutant/g-biosolids DW).

RP_a = reference annual application rate of pollutant (kg-pollutant/ha-yr), used for degradable organics.

Unlimited = calculated risk-based pollutant loadings for these media and practices were an unlimited value and therefore not of concern for public health or the environment.

Blank = pollutants for these pathways were excluded from the risk assessment based on either earlier hazard screening (e.g., hazard index, see Chapter 2), very low levels (e.g., organics in plant pathways; inorganics in volatilization pathways), or lack of an RFD for lead in Pathways 1 and 2.

Table 11

Pollutant Limits for Biosolids Identified in the Land Application Risk Assessment

Inorganic Pollutants

Pollutant	Highly Exposed Individual of Limiting Pathway	Most Limiting Pathway	Pollutant Limit (as RP_c) (kg- pollutant/ha)	Pollutant Limit (as RSC) (μg-pollutant/g-biosolids DW)[a]
Arsenic	Child Eating Biosolids	3	41	41
Cadmium	Child Eating Biosolids	3	39	39
Chromium[b]	Plant Phytotoxicity	8	3,000	3,000
Copper	Plant Phytotoxicity	8	1,500	1,500
Lead	Child Eating Biosolids	3	300	300
Mercury	Child Eating Biosolids	3	17	17
Molybdenum[c]	Animal Eating Feed	6	18	18
Nickel	Plant Phytotoxicity	8	420	420
Selenium	Child Eating Biosolids	3	100	100
Zinc	Plant Phytotoxicity	8	2,800	2,800

Organic Pollutants[d]

Pollutant	Highly Exposed Individual of Limiting Pathway	Most Limiting Pathway	Pollutant Limit (as RP_a) (ug-pollutant/g-biosolids DW, except as indicated)	Pollutant Limit (as RSC) (μg-pollutant/g-biosolids, DW)
Aldrin/Dieldrin	Adult Eating Animal Products (animals ate biosolids)	5	2.7	2.7
Benzo(a)pyrene	Child Eating Biosolids	3	15	15
Chlordane	Child Eating Biosolids	3	86	86
DDT/DDD/DDE	Adult Eating Fish/Drinking Surface Water	12	1.2(kg-poll/ha-yr)	120
Heptachlor	Adult Eating Animal Products (animals ate biosolids)	5	7.4	7.4
Hexachlorobenzene	Adult Eating Animal Products (animals ate biosolids)	5	29	29
Hexachlorobutadiene	Adult Eating Animal Products (animals ate biosolids)	5	600	600
Lindane	Child Eating Biosolids	3	84	84
n-Nitroso-dimethyl-amine	Child Eating Biosolids	3	2.1	2.1
PCBs	Adult Eating Animal Products (animals ate biosolids)	5	4.6	4.6
Toxaphene	Adult Eating Animal Products (animals ate biosolids)	5	10	10
Trichloroethylene	Child Eating Biosolids	3	10,000	10,000

[a]RSC = reference concentration of a pollutant in biosolids (μg-pollutant/g-biosolids, DW). By expressing pollutant limits as RSCs, limits for inorganic and organic pollutants can be compared (see Appendix D for conversion factors used to attain same units).

[b]Chromium may be deleted from the rule because of a court suit (see Section Q, Chapter 3).

[c]Only the ceiling concentration limit for molybdenum is currently included in the Part 503 rule pending revaluation of additional data (see Section P, Chapters 2 and 3).

[d]Limits for organic pollutants were not included in the final Part 503 rule (see Chapters 3 and 5).

Table 12
Summary of Biosolids Risk Assessment Results For Surface Disposal

Pollutant	Unlined		Lined	
	Monofill	Surface Impoundment	Monofill	Surface Impoundment
Vapor Inhalation Pathway (Pathway 1)				
Arsenic	NA[a,b]	NA	NA	NA
Benzene	6,100	3,300	6,000	3,400
Benzo(a)pyrene	unlimited	unlimited	unlimited	unlimited
Bis(2-ethylhexyl)phthalate	unlimited	unlimited	unlimited	unlimited
Cadmium	NA	NA	NA	NA
Chlordane	unlimited	unlimited	unlimited	unlimited
Chromium	NA	NA	NA	NA
Copper	NA	NA	NA	NA
DDT/DDD/DDE	unlimited	unlimited	unlimited	unlimited
Lead	NA	NA	NA	NA
Lindane	unlimited	28,000	unlimited	28,000
Mercury	NA	NA	NA	NA
Nickel	NA	NA	NA	NA
n-Nitrosodimethylamine	3,000	15	2,300	16
PCBs	unlimited	110	unlimited	100
Toxaphene	unlimited	26,000	unlimited	26,000
Trichloroethylene	unlimited	10,000	unlimited	10,000
Ground-Water Pathway (Pathway 2)				
Arsenic	140[b]	73	unlimited[c]	unlimited
Benzene	1,200	140	unlimited	unlimited
Benzo(a)pyrene	unlimited	unlimited	unlimited	unlimited
Bis(2-ethylhexyl)phthalate	unlimited	unlimited	unlimited	unlimited
Cadmium	unlimited	unlimited	unlimited	unlimited
Chlordane	unlimited	unlimited	unlimited	unlimited
Chromium	unlimited	600	unlimited	unlimited
Copper	unlimited	46,000	unlimited	unlimited
DDT/DDD/DDE	unlimited	unlimited	unlimited	unlimited
Lead	unlimited	unlimited	unlimited	unlimited
Lindane	unlimited	unlimited	unlimited	unlimited
Mercury	unlimited	unlimited	unlimited	unlimited
Nickel	unlimited	690	unlimited	unlimited
n-Nitrosodimethylamine	0.47	0.88	790	3,400
PCBs	unlimited	unlimited	unlimited	unlimited
Toxaphene	unlimited	unlimited	unlimited	unlimited
Trichloroethylene	unlimited	9,500	unlimited	unlimited

[a]NA indicates that it was not applicable to conduct a risk assessment on these pollutants for the vapor inhalation pathway because they do not tend to volatilize.

[b]Limits are expressed in milligrams per kilogram.

[c]Unlimited indicates that the calculated risk-based pollutant concentrations for those media and disposal practices were of an unlimited value and are therefore not of concern for public health or the environment.

Table 13

Pollutant Limits for Biosolids Identified in the Surface Disposal Risk Assessment

Inorganic Pollutants

Pollutant	Pollutant Limit (mg/kg)[a]	Limiting Pathway[b]
Arsenic	73	2
Cadmium	unlimited[c]	—
Chromium	600	2
Copper	46,000	2
Lead	unlimited	—
Mercury	unlimited	—
Nickel	690	2

[a]Results are from the risk assessments conducted for Class II/III ground water. Class I results are not included because EPA decided to regulate all ground water as Class II for the purposes of the Part 503 biosolids rule.

[b]Exposure pathways for surface disposal are described in Table 7 (in Chapter 2). Numbers in this column reflect results of the risk assessment for unlined surface impoundments (versus lined surface impoundments or unlined or lined monofills) because for all inorganics evaluated, this pathway resulted in the lowest limits.

[c]Unlimited indicates that the calculated risk-based pollutant values for the pollutants indicated in the media evaluated (ground water for inorganics) were of an unlimited value (i.e., no risk level identified). Risk assessments for inorganics were not conducted for the inhalation pathway because these pollutants do not tend to volatilize.

Organic Pollutants

Pollutant	Pollutant Limit (mg/kg)[a]	Limiting Pathway[b]
Benzene	140	2 (unlined surface impoundment)
Benzo(a)pyrene	unlimited[b]	—
Bis(2-ethylhexyl)phthalate	unlimited[b]	—
Chlordane	unlimited[b]	—
DDT/DDD/DDE	unlimited[b]	—
Lindane	28,000	1 (unlined or lined surface impoundment)
n-Nitrosodimethylamine	0.47	2 (unlined monofill)
PCBs	110	1 (unlined surface impoundment)
Toxaphene	26,000	1 (unlined or lined surface impoundment)
Trichloroethylene	9,500	2 (unlined surface impoundment)

[a]Pathways for surface disposal are described in Table 7 (in Chapter 2).

[b]Unlimited indicates that the calculated risk-based values for the pollutants indicated in the media evaluated (ground water and vapor for organics) had no limits (i.e., no risk level identified).

Table 14

Risk-Based Results for Biosolids Identified in the Incineration Risk Assessment

Pollutant[a]	Risk-Specific Concentration ($\mu g/m^3$)[b] (vapor inhalation pathway)
Arsenic	0.023
Cadmium	0.057
Chromium	
Fluidized-bed with scrubber	0.65
Fluidized-bed with wet scrubber and wet electrostatic precipitator	0.23
Other types with wet scrubber	0.064
Other types with wet scrubber and wet electrostatic precipitator	0.016
Nickel	2.0

[a]Only inorganic results are listed because organics are regulated in the Part 503 rule through an "operational standard" rather than pollutant limits identified in a risk assessment (see text).

[b]Risk-specific concentrations were used along with site-specific information to calculate pollutant limits (see text). Only the inhalation pathway (see Table 7) was evaluated for incineration; thus this pathway is the "limiting pathway" (see text) from which the pollutant limits were calculated.

on the different types of pollutant limits, see Appendices A and B and Boxes 9 to 14.

For some land application exposure pathways, no pollutant limit is given in Table 10. In most cases, this is because these pollutants were excluded from further evaluation during the hazard index/hazard ranking process (i.e., they were not considered toxic via that particular exposure pathway, as explained in Chapter 2). In addition, lead was not evaluated for Pathways 1 and 2 because no RfD was available. Organic pollutants were not analyzed for Pathway 8 because organics occur in biosolids at very low levels and are rarely taken up by plants at levels above background levels. Zinc and aldrin/dieldrin were not evaluated for Pathway 10 because new data indicated that they were not a concern to predators of soil organisms. For Pathway 13, no inorganic pollutants were analyzed because metals do not volatilize at ambient temperatures; therefore, levels would be negligible for this volatilization pathway.

For some pathways, the pollutant limits in Table 10 are listed as "unlimited." This means that no application (i.e., loading) rate of pollutants in biosolids (RP) was identified that would result in adverse effects via that particular pathway.

Using Exposure Pathway Pollutant Limits To Calculate Part 503 Pollutant Limits

For each pollutant evaluated, EPA considered the exposure pathway with the lowest pollutant limit as the "limiting pathway" for that pollutant for land application and surface disposal. Tables 11 and 13 list the risk assessment results for inorganic and organic pollutants for land application and surface disposal of biosolids and the associated limiting pathways. For example, for nickel in the land application risk assessment, Pathway 8 resulted in the lowest pollutant limit (RP = 420 kg of nickel/ha of land), as shown in Tables 10 and 11. This lowest pollutant limit was used directly in the Part 503 rule as the "cumulative pollutant loading rate" for nickel for land application. For other types of Part 503 pollutant limits for land application, the values identified in the risk assessment were further modified, as described in Chapter 5.

To allow comparisons between exposure pathways for land application, the pollutant limits for all inorganics in Table 10 were converted to the same unit, RP_C, as shown in Table 11 (conversions are provided in Appendix D). Note that in Table 11, the pollutant limits have been further converted to the unit RSC, so that inorganics and organics can be compared. Pollutant limits for organics are shown but were deleted from the final Part 503 rule for land application, as discussed in Chapters 3 and 5.

Detailed Risk Assessment Example: Cadmium, Pathway 2, Land Application

This section provides a detailed example of the analysis conducted for cadmium for Pathway 2 of the risk assessment for land application. This example provides a closer look at how the risk assessments were conducted, highlights how key scientific data and EPA assumptions and policy decisions were used, and illustrates why the risk assessment results are conservative.

The Highly Exposed Individual, Pathway 2

The highly exposed individual (HEI) for Pathway 2 in the land application risk assessment for the final Part 503 rule was the subsistence home gardener who over a lifetime grows a major portion of his or her diet in biosolids-amended soil. Data indicate that 5.5 percent of the U.S. population have gardens large enough to produce a major portion of their annual food consumption. Given that less than 2 percent of the U.S. population live in the same county for a lifetime, the HEI population of home gardeners for Pathway 2 is probably between 0.1 percent (5.5 x 0.02) and 2 percent of the population, with estimates pointing to less than 1 percent (Ryan and Chaney, 1993). The actual population of HEIs is probably lower because these estimates are based on short-term data and only a small number of home gardeners will garden their entire lifetime. Furthermore, to reach the estimated exposure for a 70-year lifetime, the subsistence gardener would have to continuously consume crops always produced in garden soil that contains the maximum amount of any given biosolids pollutant being evaluated (the RP) during that 70-year period. As illustrated by Ryan and Chaney (1995), this is an unlikely event.

Algorithms Used in Pathway 2

The algorithms used for Pathway 2 in the land application risk assessment were the same as those used for Pathway 1 (see Boxes 9 and 10). Because the HEI differs, however (see Table 6 in Chapter 2), the values of some of the key parameters used in Pathway 2 vary from the values used in Pathway 1, particularly for the FC and to some extent for the DC parameters. The values for each of the parameters used for cadmium in Pathway 2 are presented below, followed by a discussion of how each of the parameter values were selected; whether they are conservative or average values; and how the combination of all of the parameters contributed to making the pollutant limit (RP) conservative.

Calculation of the Adjusted Reference Intake: RIA

The first algorithm used for cadmium in Pathway 2 was:

$$RIA = \left(\frac{RfD \cdot BW}{RE} - TBI\right) \cdot 10^3 = \left(\frac{0.001 \cdot 70}{1} - 0.01614\right) \cdot 1{,}000 = 53.86\ \mu g\ Cd/day$$

Parameters Used To Calculate the RIA

Adjusted Reference Intake, RIA. The RIA represents the allowable dose of a pollutant in biosolids (e.g., in this pathway, the amount of cadmium ingested in food by the subsistence home gardener). As discussed previously in this chapter (see also Appendix B), the RIA was an important health-based parameter used in many algorithms throughout the land application risk assessment to calculate pollutant limits. The RIA value is inherently conservative because it is designed to protect sensitive members of the population based on the conservative RfD for inorganic pollutants or the q_1^* for organic pollutants (see Chapter 2, Box 3 for a discussion of why RfDs and q_1^*s are conservative). The RIA was called "adjusted" because a standard (average) adult male body weight (70 kg) was factored in, and the total background intake of pollutants from sources other than biosolids (e.g., food, water, air) was subtracted from the overall allowable dose to determine the allowable dose from biosolids. Differences in routes of exposure (e.g., ingestion versus inhalation) and bioavailability also were considered in developing the RIA (using the RE parameter, see below). All the parameters used to develop the RIA are discussed below.

Oral Reference Dose (RfD) for Cadmium. Like other inorganic pollutants in the land application risk assessment, cadmium in Pathway 2 was considered a noncarcinogen because only noncarcinogenic effects were associated with the pollutant through this pathway (food ingestion of homegrown crops). Thus, the EPA-established threshold for noncarcinogens (the RfD) for cadmium was used: 0.001 mg pollutant/kg body weight•day (or 0.070 mg Cd/70 kg body weight•day). The RfD is based on conservative data and is designed to protect even the most sensitive members of a population, based on data on the most sensitive adverse health effect. For cadmium, this value was based on the most sensitive adverse effect known to occur through oral exposure of cadmium, called renal proximal tubular proteinuria, in which low-molecular-weight proteins appear in the urine, probably indicating decreased protein reabsorption by the tubules in the kidney. Although a number of studies (Kjellstrom and Nordberg, 1978; Nogawa et al., 1978, 1987; Sharma et al., 1983) have shown that much higher levels of cadmium (e.g., ranging from 0.2 to 1.0 mg/day) could be ingested daily for a lifetime without adverse effects, the biosolids risk assessment conservatively used the RfD value of 0.07 mg Cd/70 kg body weight•day.

Human Body Weight (BW). The choice of body weight for use in the risk assessment depended on the definition of the individual at risk, which in turn depended on exposure and susceptibility to adverse effects. Because the RfD is defined as the dose of pollutant per unit of body weight that can be tolerated over a lifetime, a standard adult ("lifetime") average body weight of 70 kg was used in Pathway 2. (For the child ingestion exposure pathway, Pathway 3, an average body weight of 16 kilograms was used.) An average value for the BW parameter was considered adequate because it was combined with other, more conservative parameters (e.g., the RfD).

Relative Effectiveness of Exposure (RE). The RE parameter was used to reflect differences in toxicological effects due to differences in bioavailability and exposure routes. For example, the bioavailability of cadmium is greatly lessened when zinc is also present in the diet. Higher zinc levels in the diet of Japanese subsistence rice eaters (discussed in Box 7, Chapter 3) probably would have reduced or eliminated the intestinal absorption of cadmium and the severe *itai itai* disease experienced by this population. In addition, the binding ability of the biosolids matrix reduces the availability of biosolids metal pollutants (see also Section J-3 in Chapter 3). A policy decision was made to set the RE conservatively at 1 for the land application risk assessment. Setting RE at 1 assumes 100 percent bioavailability intake. Hence, setting the RE equal to 1 underestimates the allowable dose of biosolids pollutants.

Total Background Intake Rate of Pollutant From All Other Sources of Exposure (TBI). The background intake values for water were based on EPA reports on occurrence of and exposure to pollutants in relation to drinking water regulations, and the TBI data for dietary exposure were based on U.S. Food and Drug Administration (FDA) market basket analyses for food and liquids (except drinking water) from 1988 to 1992. Average values were used for the TBI parameter because it was combined with other, more conservative parameters. A lifetime TBI average was not based on a maximum daily intake because daily intake from background sources is variable throughout a lifetime. Hence, a TBI value represents an average estimate of pollutant intake. A TBI value for cadmium of 0.0161 mg Cd/day was used.

Calculation of the Pollutant Limit (RP)

The second algorithm used in the Pathway 2 risk assessment combined the RIA value from the first algorithm discussed above with additional parameters to calculate a pollutant limit, shown below for cadmium:

$$RP_c = \frac{RIA}{\sum(UC_i \cdot DC_i \cdot FC_i)} = \frac{53.86}{0.4408} = 122\ kg\ Cd/ha^*$$

* Listed as 120 kg Cd/ha in Table 15 due to rounding to two significant figures.

Parameters Used To Calculate the Reference Application Rate of Pollutant (RP)

Uptake Response Slope of Pollutant in Plant Tissue (UC). The UC parameter reflected the amount of a pollutant taken up by plants from soil/biosolids. This value was very important in the biosolids risk assessment for land application because it was used (in this pathway and others) to help assess human toxicity from consumption of plants containing pollutants in biosolids. The methodology used for calculating UC (for Pathways 1 and 2) was shown in Chapter 3 in the section "Calculating Plant Uptake Slopes." For Pathway 2, uptake slopes for the following seven food groups were evaluated because these were deemed likely to be grown by the home gardener (the HEI for this pathway): potatoes, leafy vegetables, fresh legumes, root vegetables, garden fruits, sweet corn, and grains and cereals. Table 15 lists the UC values for these different food groups for cadmium in Pathway 2.

A combination of conservative (very low probability of occurrence) and less conservative (low to average probability of occurrence) assumptions were used to calculate UC values in the biosolids land application risk assessment. This UC value is an overestimation of actual plant uptake because several of the key assumptions and data sets used were conservative, including: the assumption that plant response slope is linear; the use of high-metal-content biosolids data; and the use of short-term data from field studies (1 or 2 years after application), in which equilibrium had not been attained (these and other conservative assumptions used are explained below). Because of this conservatism, the geometric mean, rather than the more conservative arithmetic mean, was used to statistically represent the log normal distribution of UC data because the geometric mean provides a better estimate of central tendency for data with this type of distribution (i.e., by using the geometric mean, UC reflects median data). If the more conservative arithmetic mean had been used, a higher UC value would have resulted that reflected higher

Table 15

Parameter Values for Cadmium, Pathway 2, Land Application

Food Group	UC	DC	FC	UC · DC · FC	Other Variables	
Potatoes	0.004	15.5954	0.37	0.0230	RfD	0.001
Leafy vegetables	0.182	1.9672	0.59	0.2112	BW	70
Fresh legumes	0.002	3.2235	0.59	0.0036	RE	1
Root vegetables	0.032	1.5950	0.59	0.0305	TBI	0.01614
Garden fruits	0.045	4.1517	0.59	0.1104	RIA	53.86'
Sweet corn	0.059	1.5969	0.59	0.0552	RP_c	120
Grains and cereals	0.018	89.0833	0.0043	0.0070		
Sum UC·DC·FC				0.4408		

percentiles of the data (e.g., possibly 70th to 80th percentiles). (A median value, which is the same as the 50th percentile, is the point at which one-half of the observations of the amounts of cadmium taken up by plants are less than this value and one-half are greater than this value. The 80th percentile is the point at which 80 percent of the observed cadmium uptake values are less than this number and 20 percent are greater.)

Minimum Plant Uptake Value Used. To address data uncertainties, a minimum value of 0.001 mg/kg for plant uptake of a pollutant was assumed, even when data indicated no increase in pollutant concentration in plants or when uptake was negative. This assumption of minimum plant uptake is conservative and results in an overestimation of UC, because lower UC values would have resulted if the actual values were used. The precise degree of overestimation is unknown. For cadmium, 14 percent of the 196 data points used had plant uptake slopes of 0.001; thus, overestimation might be from 0 to 14 percent. (By comparison, 73 percent of the 52 data points for lead had UC values of 0.001, representing a much higher overestimation of risk for lead) (Ryan and Chaney, 1993).

Use of Linear Response Slope. Another conservative assumption in calculating the value for the UC parameter involved the use of a linear response slope to represent plant uptake of metals, as discussed in Chapter 3. Briefly, numerous field studies indicate that plant uptake of metals is curvilinear (i.e., increases up to a point and then levels off, or plateaus, even if more pollutant is added to the soil), given the ability of biosolids to bind pollutants in biosolids/soil mixtures. Nevertheless, the biosolids risk assessment conservatively assumed a linear response (i.e., uptake continues to increase indefinitely). The linear response slope was used because most of the individual studies used on plant uptake did not have sufficient rates of application to test for lack of linearity (Ryan and Chaney, 1993). Using a linear response slope results in an overestimate of plant uptake of metals. For cadmium in Pathway 2, overestimation was probably at least RP/20, assuming a maximum biosolids application rate of 1,000 mt/ha.

Inclusion of Acidic pH Data. The UC data included results from field studies that represented both low pH (acidic) and neutral soil conditions, even though low pH is unlikely to occur for very long (certainly not for the 70-year lifetime exposure of the HEI) because gardeners probably would quickly correct the soil pH (e.g., add lime) to improve plant health (see Chapter 3, "Ecological Risks," for a more detailed discussion on biosolids and low pH soils). In addition, increases in the solubility of two metals, aluminum and manganese, will cause injury in most plant species in low pH soil conditions, even if no additional metals are added (e.g., from biosolids). Thus, including data for low pH conditions overestimates UC values. Nevertheless, because acidic soil conditions can periodically occur, and because data show that low pH can result in phytotoxicity, plant response under acid soil conditions was included in the data set. Forty percent of the data used to calculate UC values was based on studies with a pH of less than 6.0. Using these low pH data, a garden would be strongly acidic for approximately 30 of the 70 years of HEI exposure for Pathway 2, an unlikely occurrence (Ryan and Chaney, 1993).

In addition, in the case of cadmium, if low pH conditions are not corrected (allowing for high cadmium uptake by plants), the presence of zinc (in a ratio less than or equal to 0.015 cadmium to zinc), which also is taken up by plants under low pH but otherwise normal soil conditions, will lower cadmium risks for two reasons. First, zinc is known to reduce the phytoavailability of cadmium for plant uptake. Second, the reduction in plant yield resulting from zinc toxicity would reduce potential consumption of crops containing high levels of cadmium (Fox, 1983, 1988; McKenna et al., 1992a, 1992b; Chaney and Ryan, 1994; Chaney, 1990; Logan and Chaney, 1983; Strehlow and Barltrop, 1988).

Use of Short-Term Data To Predict Long-Term Pollutant Uptake. Bioavailability of metals for plant uptake is highest in the first year after land application of biosolids (Chang et al., 1987). Nonetheless, long-term UC values (i.e., for 70 years of exposure) were conservative, based primarily on short-term data (i.e., from biosolids/soil systems established for less than 5 years) in the risk assessment. Use of these early-year data causes overestimation of long-term UC values.

Impact of Combining Conservative and Less Conservative Factors To Calculate UC. Combining the conservative factors discussed above for UC (e.g., the 0.001 bounding estimate, linearity, short-term data, and acid pH systems) with one or two less conservative factors (e.g., the geometric mean) to estimate the UC resulted in a calculated value for UC that was greater than the actual UC and, hence, overestimates risk in exposure pathways that use this parameter.

Dietary Consumption of Food Group (DC). As discussed above, the types of foods considered likely to be grown by the home gardener and therefore evaluated for this pathway were potatoes, leafy vegetables, fresh legumes, root vegetables, garden fruits, sweet corn, and grains and cereals. Determining DC values for Pathway 2 involved a methodology similar to that used for Pathway 1 (i.e., use of EPA's reanalysis of the FDA Revised Total Food Diet list to develop an Estimated Lifetime Average Daily Food Intake; see Chapter 3, "Food Consumption"), with additional revisions to account for home garden production. For example, while the Pathway 1 food group listed as "legumes" included both dried and fresh legumes, for Pathway 2 only fresh legumes were included in this category because home gardeners are unlikely to grow the dried legumes they consume. Similarly, peanuts were excluded from the Pathway 2 risk assessment (although included in Pathway 1) because home gardeners are unlikely to grow peanuts. Also, sweet corn was added as a separate category for Pathway 2 because many gardeners grow sweet corn (corn was included in Pathway 1 under the category "grains and cereals," but was subtracted from this category for Pathway 2 because home gardeners do not usually grow field corn for processing in the home). The DC values for cadmium for Pathway 2 are listed in Table 15.

The value used for the DC parameter can be considered average; however, this average DC value was based on conservative estimates (i.e., short-term dietary data was used to estimate long-term food consumption) (Ryan and Chaney, 1993). Extrapolating short-term data to long-term exposure estimates is known to result in overestimation of actual exposure (U.S. EPA, 1991). These short-term data were nevertheless used because they represented the best data available.

The subsistence home gardener HEI is likely to be at lower risk than the sensitive population that the RfD and the biosolids Pathway 2 analysis is designed to protect. This is because although the home gardener will potentially be adversely exposed to cadmium in vegetables he or she produces and consumes from his or her biosolids-amended garden soils, these same vegetables also contain significant levels of zinc, calcium, and iron, which are known to reduce cadmium absorption and hence adverse exposure. (See also Box 7 in Chapter 3.)

Fraction of Food Group Produced on Biosolids-Amended Soil (FC). The value for the FC parameter in Pathway 2 differed significantly from Pathway 1, even though the algorithms used were the same (see Boxes 9 and 10). This is because the percent of food grown for human consumption on biosolids-amended land will most likely be greater for the home gardener (the HEI for Pathway 2) than for an individual who consumes only store-bought foods, some of which are produced on biosolids-amended soils (the HEI for Pathway 1). USDA data from surveys on homegrown foods were revised to arrive at appropriate food production values for the FC parameter for Pathway 2. Assuming that 100 percent of gardeners produce some of their own food (a reasonable worst-case assumption made for the biosolids risk assessment), the revised USDA values used in the biosolids risk assessment for FC in Pathway 2 were:

Food Group	Percent Homegrown (rounded)
Potatoes[a]	37
Vegetables[b]	59
Flour, cereal	0.43

[a]Includes sweet potatoes.
[b]Includes leafy vegetables, fresh legumes, root vegetables, garden fuits (e.g., tomotos, eggplant), sweet corn.

The above values for FC are conservative because they represent the percent of homegrown garden foods for the small segment of home gardeners at the high end of the food consumption distribution. For example, it would be difficult for most home gardeners to grow 59 percent of the leafy vegetables they consume annually, given that (1) the harvesting season for leafy vegetables in most parts of the country is only several weeks long, while leafy vegetables are consumed fresh all year round, and (2) only 5.5 percent of the population have gardens large enough to produce a significant portion of their annual food consumption (Ryan and Chaney, 1993).

Thus, the conservative assumption of 59 percent homegrown production of leafy vegetables probably significantly overestimates exposure. If a more reasonable assumption of 10 percent (rather than 59 percent) annual leafy vegetable production by a home gardener were used, while retaining the 59 percent production for other foods in this food group, the pollutant limit (RP) could be increased by approximately a factor of 2 (Ryan and Chaney, 1993).

Conservative Parameters Result in a Conservative Pollutant Limit

When all of the parameter values discussed above, which are based primarily on conservative assumptions, are used together to calculate a pollutant limit (RP), it is apparent that the resultant pollutant limit is also highly conservative. In addition, it is highly unlikely that all the conservative conditions assumed would exist at the same time. For example, it is unlikely that a person would grow a large portion of the vegetables he or she consumes for an entire lifetime on biosolids-amended soil

(FC parameter) while gardening on strongly acidic soils for many years (UC parameter) and adhering to a poor quality diet that favors cadmium absorption (DC parameter) (Chaney and Ryan, 1993).

Summary. The pollutant limits identified by the biosolids risk assessments are conservative and very protective, as illustrated by the analysis done for cadmium, Pathway 2, for land application. Many of the parameters used to calculate the pollutant limits were based on conservative data sets, assumptions, and/or policy decisions including:

- ***HEI Assumption.*** The HEI for Pathway 2 grows a major portion of his or her diet on biosolids-amended soil for a lifetime. In reality, data indicate that this HEI population is small (between 0.1 to 2 percent of the U.S. population) (Ryan and Chaney, 1993). In addition, few people will have home gardens their entire lifetimes, and only a small portion of those persons will use biosolids that can produce the high soil concentrations of biosolids pollutants that would result in exposures at the pollutant limit. Equally conservative assumptions were made for many of the other pathways in the biosolids risk assessments.
- ***RfD and q_1* Data.*** RfDs and q_1*s, used in many of the exposure pathways, are based on conservative data and are designed to protect even the most sensitive members of a population, based on data on the most sensitive adverse health effect.
- ***RE Policy Decision.*** Although the ingestion route of exposure may pose less risk than other exposure routes, the relative effectiveness of exposure (RE) parameter was conservatively set at 1 because of limited data. A more accurate RE for pollutants in biosolids via food ingestion might be a value less than 1. Based on known data, the RE was considerably overestimated.
- ***UC Data and Assumptions.*** Numerous factors used to calculate plant uptake of pollutants (metals) were conservative, including:
  - Use of a minimum value (0.001 mg/kg) for plant uptake of metals (UC), even when the data showed no increase, or a decrease, in plant uptake of metals.
  - Use of a linear response slope (which assumes that plant uptake continues to increase) because of a lack of data on biosolids application rates, even though numerous data show that in reality plant uptake is curvilinear (increases initially, then levels off, or plateaus).
  - Use of data from short-term experiments in which the UC was atypically high (U.S. EPA, 1992a).
- ***FC Data.*** Use of high estimates of homegrown food consumed by the HEI for Pathway 2, particularly the 59-percent value used for leafy vegetables.
- ***Short-Term Data To Predict Long-Term Pollutant Uptake and Food Consumption.*** Short-term data were used to predict long-term uptake by plants and long-term food consumption by the HEI population for Pathway 2.
- ***Most Biosolids Cannot Exceed the Pollutant Limit for Cadmium.*** Data indicate that less than 10 percent of current biosolids, and probably less than 3 percent, could ever reach the pollutant limit for cadmium, expressed as a soil concentration limit. (This limit is known as the RLC, which is the allowed cumulative soil concentration of a pollutant in $\mu g/g$ DW; conversion of the RP pollutant application rate limit to an RLC soil concentration limit is shown in Chapter 6 and Appendix D.) In addition, it would take a minimum of 300 years (and possibly up to 600 years) of continuous application at agronomic rates (e.g., 10 mt/ha/yr) before the soil concentration of cadmium would become equal to the biosolids concentration and before it would reach the RLC. It

would also take 300 years under agronomic application rates for the upper 1 percent of biosolids (those containing the highest pollutant concentrations) to produce dietary increases in excess of the RfD. It is unlikely that continuous yearly application would occur for this time frame; therefore, soil concentrations are not likely to reach the RLC, and exposure of lifetime subsistence gardeners is unlikely to reach the RfD in any year, and even less likely for 70 years (Chaney and Ryan, 1993, 1994; Ryan and Chaney, 1995).

Summary

This chapter explains how pollutant limits were derived in the risk assessments conducted for the final Part 503 rule. Included in the discussion are descriptions of the many parameters involved and several example calculations to show how different types of parameters, models, data, and algorithms were used to calculate pollutant limits for different pathways. The conservative nature of many of the parameters also is discussed. The conservativeness remaining after combining conservative and less conservative data, assumptions, and parameters to calculate a pollutant limit is described. Finally, a detailed example is included to show the high level of protection involved in calculating a pollutant limit (cadmium in Pathway 2 for land application). While the exact degree of conservativeness varies somewhat for each of the pathways and pollutant limits developed as a result of the Part 503 risk assessments, EPA believes that all the pollutant limits conservatively protect public health and the environment from reasonably anticipated adverse effects of pollutants in biosolids. The conservative pollutant limits identified in the revised biosolids risk assessments were used to establish the pollutant limits for the final Part 503 rule, as discussed in Chapter 5.